

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte DANIEL D. VON HOFF, and
ALAN A. RUBIN

Appeal No. 2001-0992
Application No. 08/527,880

ON BRIEF

Before WINTERS, WILLIAM F. SMITH, and ADAMS, Administrative Patent
Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the
examiner's final rejection of claims 1-5, which are all the claims pending in the
application.

Claim 1 is illustrative of the subject matter on appeal and is reproduced
below:

1. A method for treating AIDS-associated non-Hodgkin's lymphoma (NHL) in a human immunodeficiency virus (HIV) positive human individual, such treatment comprising administering to the individual an effective amount of pharmaceutically acceptable gallium nitrate.

The references relied upon by the examiner are:

Warrell, Jr., et al. (Warrell I) 4,529,593 Jul. 16, 1985

Hart et al. (Hart), "Antitumor Activity and Toxicity of Salts of Inorganic Group IIIa Metals: Aluminum, Gallium, Indium, and Thallium," Proc. Natl. Acad. Sci. USA, Vol. 68, No. 7, pp. 1623-26 (1971)

Warrell, Jr., et al. (Warrell II), "Treatment of Patients with Advanced Malignant Lymphoma Using Gallium Nitrate Administered as a Seven-Day Continuous Infusion," Cancer, Vol. 51, pp. 1982-87 (1983)

Warrell, Jr., et al. (Warrell III), "Salvage chemotherapy of advanced lymphoma with investigational drugs: Mitoguazone, gallium nitrate, and etoposide," Biol. Abstr., Vol. 83, No. 7, Abstr. No. 67262 (1987)

GROUND OF REJECTION

Claims 1-5 stand rejected under 35 U.S.C. § 103 as being unpatentable over Hart in view of Warrell I, Warrell II, and Warrell III.

DISCUSSION

According to the examiner (Answer, page 3), Hart "teach the claim designated Gallium salts as old and well known for anti-tumor therapy," but does not specifically teach the treatment of non-Hodgkin's lymphoma. To make up for this deficiency, the examiner relies on Warrell I, II and III. According to the examiner (id.) Warrell I, II and III "teach non-Hodgkin's lymphoma therapy with Gallium nitrate and various other therapeutic compounds," at appellants' recited dosage (see e.g., appellants' claim 4, which requires that the gallium salt be administered parenterally in an amount ranging from 100-400 mg/sq m/day).

Based on this evidence, the examiner concludes (Answer, page 5), "[a]bsent an art recognized distinction between the claimed condition and that condition residing in the [e]xaminer cited prior art, the skilled artisan would have

been motivated to employ conventional NHL therapies to AIDS-associated NHL; enjoying a reasonable expectation of therapeutic success.”

In response, appellants argue (Brief, page 2), “that AIDS-NHL is recognized by the medical community as being different from all other lymphomas including non-AIDS non-Hodgkins Lymphoma (NHL).” To support their position appellants quote passages (Brief, pages 3-6, and Reply Brief, page 9) from a number of literature references. For example, at page 9 of their Reply Brief, appellants report the following:

- (1) Cancer: Principles and Practice of Oncology, 4th Ed., 1993.
 - AIDS-NHL differs markedly from nonAIDS-NHL, p[.] 1915
 - Standard nonAIDS-NHL chemotherapy has been unsuccessful in treating AIDS-NHL, p[.] 1916.
- (2) Medical Oncology 2nd Ed. 1993.
 - Chemotherapy developed for nonAIDS-NHL has been disappointing in treating AIDS-NHL, p[.] 1179
- (3) National Cancer Institute publication Cancer Net, 1993.
 - AIDS-NHL is very different from nonAIDS-NHL.

At page 4 of their Brief, appellants point out that:

Further confirmation of the ineffectiveness of combination therapy in managing AIDS-NHL may be observed in Example 2 of the present application. An AIDS-NHL patient was first treated unsuccessfully with combination therapies usually effective in nonAIDS-NHL (CHOP, cyclophosphamide + doxorubicin + etoposide) before obtaining an excellent response from the claimed compound, gallium nitrate.

In response to appellants’ arguments, the examiner finds (Answer, page 7) that “[a]lthough [a]ppellants elude [sic] to contraindications in the prior art ...

[a]ppellants failed to produce one contraindication, scientifically based and objective, report directing the skilled artisan not to employ conventional non-Hodgkin's lymphoma therapeutic regimens, such as the claimed gallium nitrate, to treat NHL in HIV-positive patients." It appears that the examiner is requiring appellants' to provide evidence of a direct teaching away from the use of gallium nitrate to treat AIDS-associated NHL. While a reference "teaching away" from the claimed invention is one consideration that must be given weight when evaluating the obviousness of a claimed invention¹, it is however, not the only consideration.

Another consideration that must be given weight in evaluating whether a claimed invention is obvious, is whether the prior art relied upon provides a person of ordinary skill in the art with a reasonable expectation of success. In re Vaeck, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991). On this record, appellants have provided evidence, see supra, that standard nonAIDS-NHL chemotherapy has been unsuccessful in treating AIDS-NHL. Based on the evidence of record, it is our opinion, that the evidence relied upon by the examiner does not provide a person of ordinary skill in the art at the time the invention was made with a reasonable expectation of success of treating AIDS-associated non-Hodgkin's lymphoma with gallium nitrate, as is required by the claimed invention. At best, the examiner has provided evidence suggesting that it would have been obvious to try gallium nitrate for the treatment of AIDS-

¹ In determining whether the claimed invention would have been obvious, a prior art reference must be read as a whole and consideration must be given where the reference teaches away from the claimed invention. Akzo N.V., Aramide Maatschappij v.o.f. v. United States Int'l Trade Comm'n, 808 F.2d 1471, 1481, 1 USPQ2d 1241, 1246 (Fed. Cir. 1986).

associated non-Hodgkin's lymphoma (see e.g., Answer, page 8, "[t]he prior art use of gallium nitrate to treat NHL generally would have motivated the skilled artisan to employ these compounds to treat non-Hodgkin's lymphoma in any patient population...."), obvious-to-try, however, is not the standard of obviousness under 35 U.S.C. § 103. See In re O'Farrell, 858 F.2d 894, 903, 7 USPQ2d 1673, 1680 (Fed. Cir. 1988).

Accordingly, we reverse the rejection of claims 1-5 under 35 U.S.C. § 103 as being unpatentable over Hart in view of Warrell I, Warrell II, and Warrell III.

REVERSED

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| Sherman D. Winters |) | |
| Administrative Patent Judge |) | |
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| |) | BOARD OF PATENT |
| William F. Smith |) | |
| Administrative Patent Judge |) | APPEALS AND |
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| Donald E. Adams |) | |
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